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# Safety and Efficacy of Stem Cell Therapy in Patients With Autism

**This study has been completed.**

**Sponsor:**
Shenzhen Beike Bio-Technology Co., Ltd.

**Collaborators:**
Shandong Jiaotong Hospital
Association for the Handicapped Of Jinan

**Information provided by (Responsible Party):**
Shenzhen Beike Bio-Technology Co., Ltd.

**ClinicalTrials.gov Identifier:**
NCT01343511

First received: April 26, 2011
Last updated: October 13, 2011
Last verified: October 2011
History of Changes

**Full Text View** | **Tabular View** | **No Study Results Posted** | Disclaimer | How to Read a Study Record

## Purpose

**Autism** is one of those disorders in **Autism** spectrum disorders (ASD), which characterized by social interaction abnormalities, impaired verbal and non-verbal communication, and repetitive, obsessive behavior, while the therapeutic effect of current treatments remains limited progress .Neural hypoperfusion and immune deregulation are the two key pathologies associated with **Autism**. Human umbilical **cord** mesenchymal stem cells (hUC-MSCs) and human **cord blood** mononuclear cells (hCB-MNCs) have been shown to have the ability to modulate the immune response and enhance angiogenesis, suggesting the novel and promising therapeutic strategy. In this study, the safety and efficacy of hUC-MSCs and hCB-MNCs transplantation will be evaluated in patients with **Autism**.

| Condition | Intervention | Phase |
|---|---|---|
| **Autism** | Biological: human **cord blood** mononuclear cells<br>Biological: human **cord blood** mononuclear cells and human umbilical **cord** mesenchymal stem cells | Phase 1<br>Phase 2 |

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Phase I/П Study of Stem Cell Therapy in Patients With **Autism**

**Resource links provided by NLM:**

MedlinePlus related topics: Autism Rehabilitation

U.S. FDA Resources

**Further study details as provided by Shenzhen Beike Bio-Technology Co., Ltd.:**

Primary Outcome Measures:

- Childhood **Autism** Rating Scale , CARS [ Time Frame: 6 months after treatment ] [ Designated as safety issue: No ]
- Clinical Global Impression Scale , CGI [ Time Frame: 6 months after treatment ] [ Designated as safety issue: No ]

Secondary Outcome Measures:

- Aberrant Behavior Checklist , ABC [ Time Frame: 6 months after treatment ] [ Designated as safety issue: No ]

- Adverse Event and Serious Adverse Event [ Time Frame: 6 months after treatment ] [ Designated as safety issue: Yes ]

Enrollment: 37
Study Start Date: March 2009
Study Completion Date: May 2011
Primary Completion Date: June 2010 (Final data collection date for primary outcome measure)

| Arms | Assigned Interventions |
|---|---|
| Experimental: Rehabilitation plus hCB-MNCs treatment<br>Participants will be given rehabilitation therapy plus human **cord blood** mononuclear cells transplantation with a 6 months follow-up. | Biological: human **cord blood** mononuclear cells<br>Participants will be given rehabilitation therapy plus hCB-MNCs transplantation.<br>Other Name: Group 1 |
| Experimental: Rehabilitation plus hCB-MNCs and hUC-MSCs therapy<br>Participants will be given rehabilitation therapy plus combination of hCB-MNCs together with hUC-MSCs transplantation with a 6 months follow-up. | Biological: human **cord blood** mononuclear cells and human umbilical **cord** mesenchymal stem cells<br>Participants will be given rehabilitation therapy plus and hCB-MNCs and hUC-MSCs transplantation.<br>Other Name: Group 2 |

**Detailed Description:**

To investigate the safety and efficacy of human cord blood mononuclear cells and human umbilical cord mesenchymal stem cells transplantation in patients of Autism.

## Eligibility

Ages Eligible for Study: 3 Years to 12 Years

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

**Criteria**
Inclusion Criteria:

- Children between the ages of 3 and 12 years.
- DSM-IV diagnosis of Autistic Disorder.
- Total score of CARS ≥ 30.
- Parents or legal guardian willing to sign the ICF.

Exclusion Criteria:

- Any history of hypersensitivity to serum products, or other known drug and food allergy.
- History of prior or current DSM-IV psychotic disorder (e.g., schizophrenia, bipolar disorder, other psychosis), Pervasive Developmental Disorder not otherwise specified (PDD NOS), Asperger's, or Rett's.
- History of Epileptic seizure activity in the past 6 months.
- Autism caused by seizure disorders (active), cerebrovascular disease or brain trauma.
- The global autism ratings are assessed as being absent, minimal or mild.
- Existing moderate or severe extrapyramidal symptoms (EPS) or history of tardive dyskinesia.
- Subjects who have displayed significant self-injurious behavior (children who have caused visible harm to themselves).
- HIV+
- Acute and chronic hepatitis.
- Autoimmune disease, e.g. lupus erythematosus, multiple sclerosis.
- Severe pulmonary and hematological disease, malignancy or hypo-immunity.
- Currently undertaking other treatment that may affect the safety/efficacy of stem cells.
- Enrollment in other trials in the last 3 months.
- Other criteria the investigator consider improper for inclusion.

## Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01343511

**Locations**

**China, Shandong**

Shandong Jiaotong Hospital
Jinan, Shandong, China, 250031

**Sponsors and Collaborators**

Shenzhen Beike Bio-Technology Co., Ltd.

Shandong Jiaotong Hospital

Association for the Handicapped Of Jinan

**Investigators**

Principal Investigator: Yongtao Lv Shandong Jiaotong Hospital

## More Information

No publications provided

| | |
|---|---|
| Responsible Party: | Shenzhen Beike Bio-Technology Co., Ltd. |
| ClinicalTrials.gov Identifier: | NCT01343511 History of Changes |
| Other Study ID Numbers: | BKCR-**AUTISM**-1.0(2009) |
| Study First Received: | April 26, 2011 |
| Last Updated: | October 13, 2011 |
| Health Authority: | China: Ministry of Health |

Keywords provided by Shenzhen Beike Bio-Technology Co., Ltd.:
**Autism**
human **cord blood** mononuclear cells
human umbilical **cord** mesenchymal stem cells

Additional relevant MeSH terms:
**Autistic** Disorder
Child Development Disorders, Pervasive
Mental Disorders Diagnosed in Childhood
Mental Disorders

ClinicalTrials.gov processed this record on September 22, 2013